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to a decision reversing an adverse determination of patentability and if the patent is not subject to a terminal disclaimer due to the issuance of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(b) The term of a patent entitled to extension under paragraph (a) of this section shall be extended for the sum of the periods of delay calculated under paragraphs (c)(1), (c)(2), (c)(3) and (d) of this section, to the extent that these periods are not overlapping, up to a maximum of five years. The extension will run from the expiration date of the patent.

(c)(1) The period of delay under paragraph (a)(1) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:

(i) With respect to each interference in which the application was involved, the number of days, if any, in the period beginning on the date the interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and

(ii) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Patent and Trademark Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension.

(2) The period of delay under paragraph (a)(2) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:

(i) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;

(ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under §1.193 in the application under secrecy order and ending on the date the secrecy order and any renewal thereof was removed;

(iii) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order and any renewal thereof was removed; and

(iv) The number of days, if any, in the period beginning on the date of notification under §5.3(c) and ending on the date of mailing of the notice of allowance under §1.311.

(3) The period of delay under paragraph (a)(3) of this section is the sum of the number of days, if any, in the period beginning on the date on which an appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and ending on the date of a final decision in favor of the applicant by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.

(d) The period of delay set forth in paragraph (c)(3) shall be reduced by:

(1) Any time during the period of appellate review that occurred before three years from the filing date of the first national application for patent presented for examination; and

(2) Any time during the period of appellate review, as determined by the Commissioner, during which the applicant for patent did not act with due diligence. In determining the due diligence of an applicant, the Commissioner may examine the facts and circumstances of the applicant's actions during the period of appellate review to determine whether the applicant exhibited that degree of timeliness as may reasonably be expected from, and which is ordinarily exercised by, a person during a period of appellate review.

[60 FR 20228, Apr. 25, 1995]

§1.710 Patents subject to extension of the patent term.

(a) A patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of this subpart.

(b) The term *product* referred to in paragraph (a) of this section means—

(1) The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(2) The active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

[54 FR 30379, July 20, 1989]

§ 1.720 Conditions for extension of patent term.

The term of a patent may be extended if:

(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;

(b) The term of the patent has never been previously extended except for any interim extension issued pursuant to § 1.760;

(c) An application for extension is submitted in compliance with § 1.740;

(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

(e) The product has received permission for commercial marketing or use and—

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent has not expired before the submission of an application in compliance with § 1.741; and